In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-481V
Filed: March 19, 2019
PUBLISHED

JOANNE GURNEY, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Processing Unit (SPU); Ruling on Entitlement; Table Injury; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for petitioner.
Julia Marter Collison, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

Dorsey, Chief Special Master:

On April 4, 2017, petitioner filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,[2] (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") following receipt of her October 1, 2015 influenza ("flu") vaccination. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons described below the undersigned now finds that petitioner is entitled to compensation for a SIRVA.

[1] The undersigned intends to post this ruling on the United States Court of Federal Claims' website. **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this unpublished ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services).

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

After filing her petition, petitioner filed medical records marked as Exhibits 1 to 9 on April 14, 2017. (ECF No. 7.) Affidavits by petitioner were filed as Exhibits 10 and 11. (ECF No. 8.) Additional records were filed as Exhibits 12 to 14 on May 15, 2017. (ECF No. 10.)

The initial status conference was held with the staff attorney managing this case on June 23, 2017. (ECF No. 13.) At that time, respondent's counsel indicated that her client intended to defend the case, stressing that petitioner did not seek treatment for her alleged SIRVA until six months after her vaccination. (*Id*.) Respondent requested further evidence corroborating petitioner's affidavit which described reasons, including ongoing dental care, for her delay in seeking treatment. (*Id*.)

On August 7, 2017, petitioner filed dental records as Exhibits 15 to 17. (ECF No. 14.) On August 21, 2017, petitioner filed a supplemental affidavit as Exhibit 18 and witness affidavits as Exhibits 19 (Michael Gurney) and 20 (Diane Edmond). (ECF No. 17.) She also filed a copy of her paid leave report as Exhibit 21. (ECF No. 18.)

A further status conference was held with the staff attorney managing this case on September 21, 2017. (ECF No. 21.) At that time, respondent indicated that petitioner's supplemental filings did not alter respondent's position in the case. (*Id*.)

Respondent filed his Rule 4(c) Report on October 31, 2017. (ECF No. 22.) Respondent contended that petitioner's injury could not constitute a Table Injury SIRVA, because there is no documentation showing that petitioner exhibited symptoms of SIRVA within 48 hours of vaccine administration and none of her medical records describe her pain as occurring within 48 hours of vaccination. (*Id*. at 8.) With regard to a potential cause-in-fact claim, respondent argued that petitioner failed to provide evidence of a logical sequence of cause and effect, that she had no medical or expert opinion to support her claim, and that petitioner's medical records contradict or are insufficient to prove a temporal association between her injury and her vaccination. (*Id*. at 9.)

Thereafter, a video fact hearing was set for March 13, 2018.[3] (ECF No. 25.) In advance of the hearing, petitioner filed additional witness affidavits by Dr. Marc Wladis (Exhibit 22), Renee Gurney (Exhibit 23), and Jane T. Sears (Exhibit 24). (ECF Nos. 27, 32.) Petitioner also filed a further supplemental affidavit as Exhibit 25. (ECF No. 32-3.) On March 29, 2018, the fact hearing was held. (*See* Transcript of Proceedings ("Tr.") March 29, 2018 (ECF No. 40).) Petitioner and her husband, Michael Gurney, testified. (*Id*.)

Subsequently, the undersigned held a post-hearing status conference on April 3, 2018. (ECF No. 38.) At that time the undersigned indicated that "she finds petitioner to be a credible witness and that her testimony is credible and reasonable regarding her delay in seeking treatment of her shoulder injury. Although the delay in seeking

[3] It was subsequently rescheduled for March 29, 2018, due to inclement weather at petitioner's location. (ECF No. 35.)

treatment could be a factor in assessing petitioner's damages, it does not defeat petitioner's claim." (*Id*. at 1) Nonetheless, the undersigned indicated that expert opinion would be necessary to address the significance, if any, of potential aggravating incidents discussed in petitioner's testimony as well as symptoms of numbness, tingling, and neck pain described in petitioner's testimony.[4] (*Id*.) The undersigned further indicated that she "would like to see an orthopedic expert opinion regarding whether petitioner's symptoms could be attributed solely to her vaccination, solely to her traumas, or to a combination of the two. The expert should also opine on the significance of petitioner's description of numbness, tingling, and neck pain." (*Id*. at 2.)

Petitioner filed updated medical records as Exhibit 26 on May 21, 2018. (ECF No. 41.) She filed an expert report by Marco Bodor, M.D., on May 24, 2018, as Exhibit 27, with supporting literature marked as "Tabs" A to D. Dr. Bodor's curriculum vitae was filed as Exhibit 28.[5] (ECF No. 43.)

On August 29, 2018, respondent filed a responsive expert report by Robert Brophy, M.D., as Exhibit A, with supporting materials filed as "Tabs" 1 and 2. Dr. Brophy's curriculum vitae was filed as Exhibit B.[6] (ECF No. 49.) Petitioner filed a supplemental expert report by Dr. Bodor on October 24, 2018, as Exhibit 29. (ECF No. 52.) Supporting medical literature was filed as Exhibits 30 to 45. (ECF Nos. 52-53.)

Thereafter, respondent requested an opportunity to file a further response to petitioner's supplemental expert report and requested a hearing. (ECF No. 56.) The

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[4] In fact, petitioner did not actually reference numbness. She described some tingling in her fingers and a "strange sensation" that she compared to the squeezing of an elastic band above the elbow. (Tr. 69.)

[5] Of note, Dr. Bodor's listed publications includes "Vaccination related shoulder dysfunction," a paper appearing in the January 8, 2007 volume of *Vaccine*. Respondent cited this research when proposing to add SIRVA to the Vaccine Injury Table. 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015. Dr. Bodor is a doctor of physical medicine and rehabilitation. (Ex. 28, p. 1.) He is licensed to practice medicine in California and is board certified in physical medicine and rehabilitation, with subspecialties in pain management and sports medicine. He is also board certified in neuromuscular and electrodiagnostic medicine. (Ex. 28, p. 1.) Dr. Bodor earned his medical degree at the University of Cincinnati Medical School in 1987 and subsequently completed an internship in surgery at the University of California, San Diego, and a residency in physical medicine and rehabilitation at the University of Michigan. (*Id*.) He previously held positions as an emergency physician and attending physiatrist from 1988 through 1994. Since 1995 he has practiced as an interventional physiatrist in private practice. (Ex. 28, p. 1.) Additionally, Dr. Bodor is an assistant professor in the Department of Neurological Surgery at the University of California, San Francisco, Medical Center and team physician for the Napa Valley College Athletic department. (*Id*.)

[6] Dr. Brophy is a professor of sports medicine in the Department of Orthopaedic Surgery at the Washington University School of Medicine in St. Louis, Missouri. (Ex. B, p. 1.) He has been teaching at the Washington University School of Medicine since 2007. (*Id*.) He is licensed to practice medicine in the state of Missouri and is a diplomate of the American Board of Orthopedic Surgery with a Certificate of Added Qualifications in sports medicine. (*Id*.) Dr. Brophy earned his medical degree at the Washington University School of Medicine in 2001. (Ex. B, p. 1.) Subsequently he completed an internship in orthopedic surgery and general surgery at New York Presbyterian Hospital in New York City, following by a residency in orthopedic surgery and a fellowship in sports medicine and shoulder surgery at the Hospital for Special Surgery in New York, New York. (*Id*.) Dr. Brophy lists a multitude of peer reviewed publications on his curriculum vitae. (Ex. B, pp. 6-29.) Like Dr. Bodor, a number of these publications are related to shoulder conditions.

undersigned allowed respondent the opportunity to file the requested response, but declined to proceed with a hearing, indicating that "[a]t this time the undersigned does not believe that a further hearing will be necessary to resolve entitlement in this case."[7] (ECF No. 57.)

Respondent filed a supplemental expert report by Dr. Brophy on December 19, 2018. (ECF No. 58.)

Petitioner filed a motion for a ruling on the record on February 27, 2019. (ECF No. 60.) Respondent's response was due by March 13, 2019, but respondent filed no response.

Accordingly, this case is now ripe for the undersigned's ruling on entitlement.

I. Legal Standard

Under the National Vaccine Injury compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, such as the present one, the petitioner may seek simply to demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown by the government that the injury was caused by some factor other than the vaccination.[8] (§ 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).)

As relevant here, effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule, 82 Fed. Reg. 6294, Jan. 19, 2017; National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date, 82 Fed. Reg. 11321, Feb. 22, 2017

[7] The Vaccine Act provides that the special master "may conduct such hearings as may be reasonable and necessary. §12(d)(3)(B)(v). Pursuant to the Vaccine Rules, "[t]he special master may decide a case on the basis of written submissions without conducting an evidentiary hearing." Vaccine Rule 8(d). The special master determines the format for taking evidence "based on the specific circumstances of each case." Vaccine Rule 8(a).

[8] Where the Table presumption is unavailable, petitioner may alternatively demonstrate causation-in-fact without any presumption of causation as explained in *Althen v. Sec'y of Health & Human Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005), which set forth a three pronged test for evaluating causation-in-fact claims. For the reasons discussed below, it is not necessary to reach the question of whether petitioner has established causation-in-fact.

(delaying the effective date of the final rule until March 21, 2017). The criteria under the QAI are as follows:

> A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

82 Fed. Reg. 6303 (Qualifications and Aids to Interpretation for SIRVA); *see also* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052).

II. Analysis

Based on the record as a whole, including the medical records, testimony, witness statements, and expert reports with supporting literature, the undersigned finds preponderant evidence that petitioner suffered a Table SIRVA. As noted above, the undersigned found petitioner credible in her testimony regarding the onset of her condition, but felt that expert opinion was necessary to speak to what, if any, significance could be attributed to two possible aggravating incidents as well as petitioner's testimony that she experienced tingling and neck pain. Upon review of the expert reports filed in this case, the undersigned is persuaded that the evidence of record does not suggest that any of these factors defeat petitioner's claim.

The facts at issue in this case need not be repeated at length. Petitioner received an influenza vaccination in her left deltoid at her primary care physician's office on October 1, 2015. (Ex. 1, p. 2.) Neither petitioner's testimony nor her medical records indicate any history of prior shoulder complaints or symptoms. On March 31, 2016, petitioner presented to her primary care doctor complaining of "[left] shoulder limitations severe pain, want to know if the flu shot she [had] could of [sic.] had a reaction." (Ex. 2, p. 4.) An orthopedist later diagnosed her with adhesive capsulitis. (Ex. 4, pp. 1-5.) An MRI conducted April 15, 2017, showed "[f]ocal superficial partial thickness undersurface tear involving the region of the posterior fibers of the supraspinatus tendon and anterior fibers of the supraspinatus tendon. There is nonspecific subcortical cystic change noted at this level within the humeral head. There is mild subacromial/subcortical bursitis. Non-detached tear of the superior anterior to posterior labrum." (Ex. 12, pp. 7-8.) Prior to seeking treatment for her shoulder pain, petitioner testified that she experienced two possible aggravating incidents, a fall on the stairs and pain when pulling on a car fender. (See, e.g. Tr. 16-18, 71-72.) Additionally, petitioner testified that she

experienced neck pain as well as tingling in her fingers and a strange sensation similar to the squeezing of an elastic band. (*See, e.g.* Tr. 12-13, 69, 72.)

Pursuant to the Vaccine Act, the special master may find the time period for the first symptom or manifestation of onset required for a Table injury is satisfied "even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such a period." § 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset . . . occurred within the time period described in the Vaccine Injury Table." *Id.*; *accord Tenneson v. HHS*, No. 16-1664V, 2018 WL 3083140, at *5 (Fed. Cl. Spec. Mstr. Mar. 30, 2018) (finding, despite prior records indicating non-tender extremities, that "respondent unreasonably dismisses petitioner's contemporaneous treatment records since the records were not created contemporaneously with the onset of petitioner's shoulder pain.").

Based on a review of the testimony and medical records in this case, the undersigned finds preponderant evidence that the onset of petitioner's shoulder pain occurred within 48 hours of vaccination. Although petitioner waited almost six months before seeking treatment, her first treatment record explicitly attributed her pain to her flu vaccination. Specifically, as noted above, on March 31, 2016, petitioner's primary care physician recorded a history of "[left] shoulder limitations severe pain, want to know if the flu shot she [had] could of [sic.] had a reaction." (Ex. 2, p. 4.) Her orthopedic records were less precise; however, her physical therapist recorded that petitioner "presents with long [history of] left shoulder pain that she relates to a flu shot." (Ex. 3, p. 4.) Additionally, petitioner submitted an affidavit by Dr. Marc Wladis, a cataract surgeon and petitioner's employer. (Ex. 22; Tr. 5.) Dr. Wladis recalled that petitioner "noticed significant pain in her shoulder area immediately after receiving the shot." (*Id.*)

Dr. Wladis also indicated that he spoke with petitioner about her shoulder pain after her vaccination and that he urged her to be patient and that her symptoms would likely resolve with time. (Ex. 22.) In addition, petitioner described other reasons why she delayed seeking treatment. In the undersigned's experience, this is not unusual among those experiencing a SIRVA. *See, e.g. Cooper*, 2018 WL 1835179, *2 (noting that petitioner described a delay in seeking treatment due to an extended trip to Vietnam and care for her ailing mother); *Marino v. HHS*, 16-622V, 2018 WL 2224736, at *2 (Fed. Cl. Spec. Mstr. Mar. 26, 2018) (noting a delay in seeking treatment due to a busy work schedule and difficulty making appointments); *Almanzar v. HHS*, No. 16-340V, 2017 WL 8220616, at *3 (Fed. Cl. Spec. Mstr. Dec. 21, 2017) (noting delay in treatment due to difficulty scheduling appointments and snow storms); *Knauss v. HHS*, 16-1372V, 2018 WL 3432906 (Fed. Cl. Spec. Mstr. May 23, 2018)(noting three month delay in seeking treatment without a specified reason).

Medical records generally "warrant consideration as trustworthy evidence." *Cucuras v.HHS,* 993 F.2d 1525, 1528 (Fed.Cir.1993). Notwithstanding that the precise onset is not recorded or that some records may be silent as to the cause of petitioner's

shoulder pain, based on the record as a whole the undersigned finds preponderant evidence in petitioner's contemporaneous treatment records supporting her testimony linking the onset of her shoulder pain to her vaccination.[9] Moreover, the undersigned found petitioner to be a credible witness and her testimony, which remains consistent with the medical records, explicitly places the onset of her shoulder pain within 48 hours of vaccination. (*See, e.g.* Tr. 11-16.) Petitioner described pain during the night following her vaccination that prevented her from sleeping on her left side. (Tr. 11.) She described significant muscle ache in her shoulder the next day. (Tr. 12-13.)

In addition, petitioner's claim is supported by expert opinion persuasively suggesting that petitioner suffered a SIRVA. Petitioner's expert, Dr. Bodor, opined that "[b]ased on my review of the records, including the 148-page transcript of March 29, 2018, Ms. Gurney sustained an injury to her shoulder at the time of her vaccination on October 1, 2015. This was caused by both needle trauma and an antigen-mediated inflammatory response followed by adhesive capsulitis (frozen shoulder), which appears to continue to the present time based on limitations of raising her arm and reaching when asked to do so during her hearing of March 29, 2018." (Ex. 27, p. 2.) Dr. Bodor further indicated that petitioner's later MRI showed abnormalities at the location of the infraspinatus-supraspinatus tendon insertion, which he opined is consistent with the manner of injection petitioner described in her testimony. (Ex. 27, p. 2.) Dr. Bodor opined that the manner of injection, combined with petitioner's low BMI[10] of 21.4, increased the likelihood that the injection penetrated into the bursa as well as the teres minor and infraspinatus tendons of the rotator cuff at their insertions on the humerus.[11] (*Id*.)

With regard to petitioner's testimony that she experienced tingling and neck pain, Dr. Bodor suggested that these symptoms may either be secondary to referred pain from needle trauma and inflammation or they may be secondary to the development of

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[9] In weighing medical records, "it must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant." *Murphy v. HHS*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991)(*aff'd* 968 F.2d 1226 (Fed. Cir. 1992)). Moreover, the undersigned has previously observed in prior SIRVA cases that histories of present illness reported by patients may include imprecise or generalized recollections of onset that should not be overanalyzed where they are consistent with the appropriate timeframe. *Cooper*, 2018 WL 1835179, n. 13.

[10] "BMI" refers to Body Mass Index. Dorland's Illustrated Medical Dictionary, 32nd Ed., p. 231.

[11] Of note, this opinion is also consistent with literature filed by respondent and relied upon by respondent's expert, Dr. Brophy. *See* Ex. A, Tab 2 (Arias, et al), p. 5 (stating that "[t]he utilization of a needle longer than those indicated in the above paragraph according to the patient's body weight may result in an excessively deep penetration into the muscle, so that the needle may reach the subdeltoid and subacromial bursae due to the close proximity of these anatomical structures, which, in turn, may cause shoulder capsule inflammation (capsulitis). This excessive penetration depth may damage even the glenohumeral joint and the humeral head.")

cervical radiculopathy as a result of petitioner compensating for her reduced range of motion in her shoulder. (Ex. 27, p. 3.) He noted, however, that numbness and tingling are non-specific in the setting of a normal neurological exam.[12] (Ex. 29, p. 3.) Significant in that regard, although petitioner mentioned tingling in her testimony, she never reported such symptoms to her physicians. To the extent petitioner did complain to her physicians of neck pain, in her testimony she attributed that pain to her sleep position and testified that she did not associate it with her shoulder pain. (Tr. 12-13.) Moreover, despite her report of some neck symptoms, her orthopedist did not relate her neck pain to her shoulder injury and her treating diagnosis was consistently adhesive capsulitis, a diagnosis limited to the shoulder and with which both experts agree. Nor did the orthopedist diagnose her with any separate condition of the neck or spine. Accordingly, the undersigned does not find petitioner's reports of tingling or neck pain constitute a condition or abnormality that would explain petitioner's SIRVA symptoms.

With regard to the fender pulling and staircase fall incidents described by petitioner, Dr. Bodor opined that these incidents would have been unlikely to cause petitioner pain if she had not already had a vaccine-related shoulder injury. (Ex. 27 at 3-4.) Additionally, both Dr. Bodor and Dr. Brophy opined that petitioner's superior anterior-posterior labral tear evidenced on her MRI was mostly likely a pre-existing condition rather than being caused by these incidents.[13] (Ex. 27, pp. 2-3. Ex. A, p. 5.) Moreover, when seeking treatment for her shoulder injury, petitioner attributed her shoulder pain to her vaccination and not to these other incidents. *Accord Cucuras*, 993 F.2d at 1528 (noting that medical records "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium.")

To the extent Dr. Brophy offered opinions contrary to those of Dr. Bodor, the undersigned found Dr. Brophy's reports less persuasive overall. Indeed, much of Dr. Brophy's reports are devoted to discussing the nature of adhesive capsulitis and whether it can be considered vaccine-caused in this or in any case. Specifically, Dr. Brophy opined that "Ms. Gurney suffered from a diagnosis of left shoulder adhesive capsulitis, most likely idiopathic. Idiopathic adhesive capsulitis, commonly known as

[12] Respondent's expert, Dr. Brophy, disputed the possibility of referred pain, but noted that "patients often have overlap of shoulder, neck and nerve complaints." (Ex. A, p. 6.) He did not opine that petitioner's reports of neck pain or numbness and tingling suggested that her diagnosis of adhesive capsulitis was incorrect or that these report suggested a different etiology for her shoulder symptoms. For example, Dr. Brophy agreed that there is no evidence that petitioner suffered from a pain syndrome. (Ex. C, p. 4.)

[13] Importantly, however, it is clear from the record as a whole that petitioner was asymptomatic prior to receipt of her influenza vaccination. Thus, notwithstanding the MRI findings, there is "[n]o history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection." Dr. Brophy suggested the possibility that pulling on the car fender represented "a microtrauma to the shoulder joint that was the inciting event leading to the development of adhesive capsulitis," but did not point to any specific findings that would support that possibility. (Ex. A, p. 4.)

frozen shoulder, has an overall incidence of 3 to 5 percent, peaking between the ages of 35 to 65 and more common in females than males." (Ex. A, p. 3.) He further opined that "there is limited evidence that a flu shot can cause adhesive capsulitis." (*Id*. at 4.) Although Dr. Brophy acknowledged that there is scientific literature linking the vaccination and the development of frozen shoulder, he indicated that "[t]he problem with these cases is that temporal association does not equate with causation." (*Id*.)

However, since Dr. Brophy's opinion is that petitioner's condition is better explained as *idiopathic* adhesive capsulitis, it necessarily fails to meet respondent's burden of showing the presence of a factor unrelated to vaccination. 13(a)(2)(A)(indicating that "the term 'factors unrelated to the administration of the vaccine – does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition.") And, in any event, to establish a Table SIRVA, petitioner does not bear any burden to affirmatively prove that her adhesive capsulitis was caused by her vaccine. Her burden is to prove the elements of SIRVA as set forth in the QAI along with satisfying the timing requirements of the Vaccine Injury Table. Nothing in the QAI for SIRVA requires the presence of any specific orthopedic diagnosis and adhesive capsulitis is compatible with SIRVA. Significant in that regard, when proposing to add SIRVA to the Vaccine Injury Table, respondent specifically identified adhesive capsulitis or frozen shoulder syndrome as "diagnoses, beyond deltoid bursitis, that resulted in shoulder pain following vaccination." National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015.

III. Conclusion

For all the foregoing reasons, the undersigned finds that petitioner has demonstrated by preponderant evidence that she suffered a SIRVA within the definition of the Vaccine Injury Table Qualification and Aids to Interpretation and that the first manifestation or symptom of her SIRVA occurred within 48 hours of her October 1, 2015 flu vaccination. Accordingly, petitioner is entitled to compensation for her SIRVA.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master